

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2891. Adulteration and misbranding of vitamin B₁ injection. U. S. v. 804 Vials.
* * * (F. D. C. No. 27696. Sample No. 7880-K.)

LIBEL FILED: August 18, 1949, Western District of New York.

ALLEGED SHIPMENT: On or about April 15, 1949, by Apco Laboratories, Inc., from Newark, N. J.

PRODUCT: 804 10-cc. vials of *vitamin B₁ injection* at Buffalo, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Thiamine Hydrochloride Injection" (vitamin B₁), a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use. The article was misbranded in interstate commerce.

DISPOSITION: September 12, 1949. Default decree of condemnation and destruction.

2892. Misbranding of Crest Foot Ointment. U. S. v. 17 Cases * * *.
(F. D. C. No. 27595. Sample Nos. 52021-K, 52022-K.)

LIBEL FILED: July 21, 1949, Northern District of Ohio.

ALLEGED SHIPMENT: On or about June 29 and July 1, 1949, from Huntington, W. Va., and Chicago, Ill.

PRODUCT: 17 cases, each containing 12 14-ounce jars, of *Crest Foot Ointment* at Cleveland, Ohio, in possession of Ben Garber.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, and verbal statements, made by the consignee while offering the article for sale, contained misinformation concerning the article. The article was misbranded in the above respect while held for sale after shipment in interstate commerce.

DISPOSITION: September 7, 1949. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2893. Adulteration of iron sulfate solution. U. S. v. 2 Barrels, etc. (F. D. C. No. 27598. Sample Nos. 1676-K, 1685-K, 1686-K.)

LIBEL FILED: July 28, 1949, Western District of South Carolina.

ALLEGED SHIPMENT: Between the approximate dates of September 20, 1947, and November 15, 1948, from Bay Springs and Louin, Miss.

PRODUCT: 21 50-gallon barrels of *iron sulfate solution* at Union, S. C.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence

of mold. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 1, 1949. Default decree of condemnation and destruction.

2894. Adulteration of mineral salts solution. U. S. v. 1 Barrel * * *
(F. D. C. No. 27434. Sample No. 53494-K.)

LIBEL FILED: June 27, 1949, Middle District of Alabama.

ALLEGED SHIPMENT: On or about February 23, 1949, from Bay Springs, Miss.

PRODUCT: 1 25-gallon barrel of *mineral salts solution* at Montgomery, Ala. Examination showed that the product was a water solution of ferric sulfate and was contaminated with mold.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: July 22, 1949. Default decree of condemnation and destruction.

2895. Adulteration and misbranding of Heintzelman's Famous Swedish Elixir Of Life (Formula No. 1620). U. S. v. 2 Drums, etc. (F. D. C. No. 27844. Sample Nos. 13807-K, 13808-K.)

LIBEL FILED: September 16, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 17, 1948, and June 24, 1949, from New York, N. Y.

PRODUCT: *Heintzelman's Famous Swedish Elixir Of Life (Formula No. 1620)*. 2 drums and 37 retail cartons at Philadelphia, Pa., in possession of Heintzelman's Pharmacy, Inc., together with a number of circulars entitled "Dr. Heintzelman's Famous Swedish Elixir Of Life." The 37 retail cartons were prepared by repacking a portion of the product contained in the drums. Analysis showed that the product in the drums and cartons was a coarsely ground mixture of plant parts, including aloe, agaric, myrrh, gentian, galangal, rhubarb, American saffron, and laurel.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the portion of the article contained in the retail cartons consisted in whole or in part of a filthy substance by reason of the presence of insects. This portion was adulterated while held for sale after shipment in interstate commerce.

Misbranding, Section 502 (a) certain statements in the labeling of the article in the drums and cartons, namely, on the carton label and in the circulars, were false and misleading. The statements represented and suggested that the article was effective in the treatment of bilious and gastric attacks, liver and kidney complaints, dyspepsia, hypochondria, gout, yellow jaundice, headache, and various forms of nervous and rheumatic complaints; that daily use of the article would establish a long and healthy life, invigorate the body and mind, and give relief to all nervous and rheumatic complaints; that it would cleanse the stomach and liver, increase the appetite, promote digestion, and remove all colic and bilious affections; and that it was an effective remedy for worms in children and adults and for hysterical affections of women and women's complaints. The article was not effective in the treatment of the conditions or for the purposes stated and applied. The